Exhibit J

11:37:18 This is what the judge will or has instructed you as far as the risk/benefit test. You have to balance the inherent risk of harm against the utility or benefits of the product design.

11:37:38 And you also have to determine whether Bard exercised reasonable care in choosing the design for a product.

Ladies and gentlemen, I would submit to you that the most powerful evidence on this issue, whether these designs, or this design, was defective, comes straight from the words 11:38:04 of the FDA.

I urge you if there's any question in your mind to look at Exhibit 5877 when you get back to the jury room.

5877 is the memo written by an FDA official. In 1996, when the agency was deciding whether to down classify 11:38:29 filters from Class III to Class II, and the agency determined that they were going to down classify these filters despite the fact that there were clearly risks associated with them.

And they recognized that the complications or risks were potentially life-threatening, but that the disease these 11:39:01 filters is supposed to treat, pulmonary embolism, is also life-threatening. And even aware of the very risks that the plaintiff's attorney is complaining about in this courtroom, even aware that those risks will occur, the FDA determined that it was not an unreasonable risk of illness and injury 11:39:28 because of the benefits of these devices. And the agency made

that risk/benefit calculation even knowing that migration could occur and reporting that migration with these devices could occur between 6 and 53 percent of the time.

Also noting, as all the evidence has indicated here, that minor filter migration is commonly reported and does not appear to be associated with clinically significant events.

In other words, the agency decided to down classify these filters even knowing there was this significant risk of migration. And also knowing that there was a significant risk of fracture.

The FDA noted that fracture is usually asymptomatic and requires no treatment. And noted that the incidents of fracture had been reported as 2 percent in the literature.

And despite knowing that that risk of fracture was there, the agency determined that the benefits of these devices was sufficiently great and outweighed those risks so that the agency down classified the device.

And the FDA maintains that view.

We showed you that as recently as 2010, the FDA issued a public health notice, directed to doctors, talking about the fact that people with retrievable filters need to be monitored to see whether the device is ready to be removed. And in that notification, once again, 14 years after the down classification, the agency recognized that there are long-term risks associated with these devices. And those risks include